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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/863,803 | 05/22/2001 | Jeffrey J. Rade | 71699/55591 | 8907 |

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| EXAMINER | |
|---|---|
| LI, QIAN J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1632 | 11 |

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Advisory Action | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/863,803 | RADE ET AL. | |
| | Examiner | Art Unit | |
| | Q. Janice Li | 1632 | |

*--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

THE REPLY FILED 14 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *See Continuation Sheet*.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *1,3-12 and 14-28*.

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Continuation of 2. NOTE: The proposed amendment would add new limitation to the claims, i.e. when using TM, at least one of EPCR or NF-KB inhibitor has to be co-expressed. The amendment would therefore require further consideration.

Continuation of 5. does NOT place the application in condition for allowance because:

Claims 1, 3-12, and 14-28 stand rejected, under 35 USC §112, first paragraph pertains to Written Description and Enablement requirement for reasons of record and following.
In paper #11, applicants argue in addition to reiterate the arguments of paper #8, that in Summary section, EPCR has been mentioned more than one time, and numerous references have been referred to in the specification page 17 for the functional fragment of TM. The arguments have been fully considered but found not persuasive because merely reciting "EPCR" multiple times does not provide adequate written description for the "functional fragments" of the EPCR.
Although numerous publications concerning TM are cited in the specification or could be found in the relevant art, they do not necessarily teach the "functional fragment" of TM. For example, most of the more than ten references cited in page 17 were published in early 1980s, before the '207 patent, which does not teach the functional fragments of TM. The Cadroy reference (1997) teaches measuring TM activity in endothelial cells, and fails to teach functional fragment of TM. The Ohlin reference (1997) is a case study, teaches a TM gene mutation in a patient, again, does not teach the functional fragment of the TM. To the extent that the materials used in the claimed method are not described in the instant disclosure, claims are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been adequate described. Therefore, for reasons of record and those set forth above, the rejection stands.

With respect to the therapeutic aspect of the enablement rejection, Applicants argue that Kim et al admitted it was a surprise that the expression of EPCR was not reduced in the untreated grafts. In response, it illustrated the unpredictable nature of the art. The remaining arguments are moot because they are drawn to amended claims. Applicants are reminded that the amendments have not been entered.

Claims 1, 3-6, 8-12, 14-22, and 24-27 stand rejected under 35 U.S.C. 102(e) as being anticipated by French et al (US 6,290,949). The arguments presented are drawn to amended claims, and thus moot, because the proposed amendments have not been entered.

Claims 1, 3-6, 8-12, 14-23, and 24-28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over French et al (US 6,290,949) as applied to claims 1, 3-6, 8-12, 14-22, and 24-27 above, and in view of Larson et al (US 6,309,380). The arguments presented are drawn t amended claims, and thus moot, because the proposed amendments have not been entered.

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER